

Expression of uncertainty

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The ability to highlight and communicate scientific uncertainties is of paramount importance

Draft DG SANCO Discussion Paper

Decision-makers need to be aware of the degree of uncertainty attached to the results of the evaluation of the available scientific information.

**European Commission Communication
on the precautionary principle**

It is ... very important for the risk manager to have a feeling for the level of uncertainty or confidence in the advice.

Robert Madelin to non-food Committees, 2004

... uncertainties ... should be explicitly considered at each step in the risk assessment process and documented in a transparent manner.

Expression of uncertainty or variability in risk estimates may be qualitative or quantitative, but should be quantified to the extent that is scientifically achievable.

Responsibility for resolving the impact of uncertainty on the risk management decision lies with the risk manager, not the risk assessors

Codex Working Principles for Risk Analysis

SANCO has decided to...ask for an assessment of ... degrees of uncertainty (a qualitative more often than a quantitative assessment)

...must not result in opinions concentrating on the degree of uncertainty to the exclusion of giving advice

...several types and levels of uncertainties that should all be communicated in ... each risk assessment

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Assessment of uncertainties

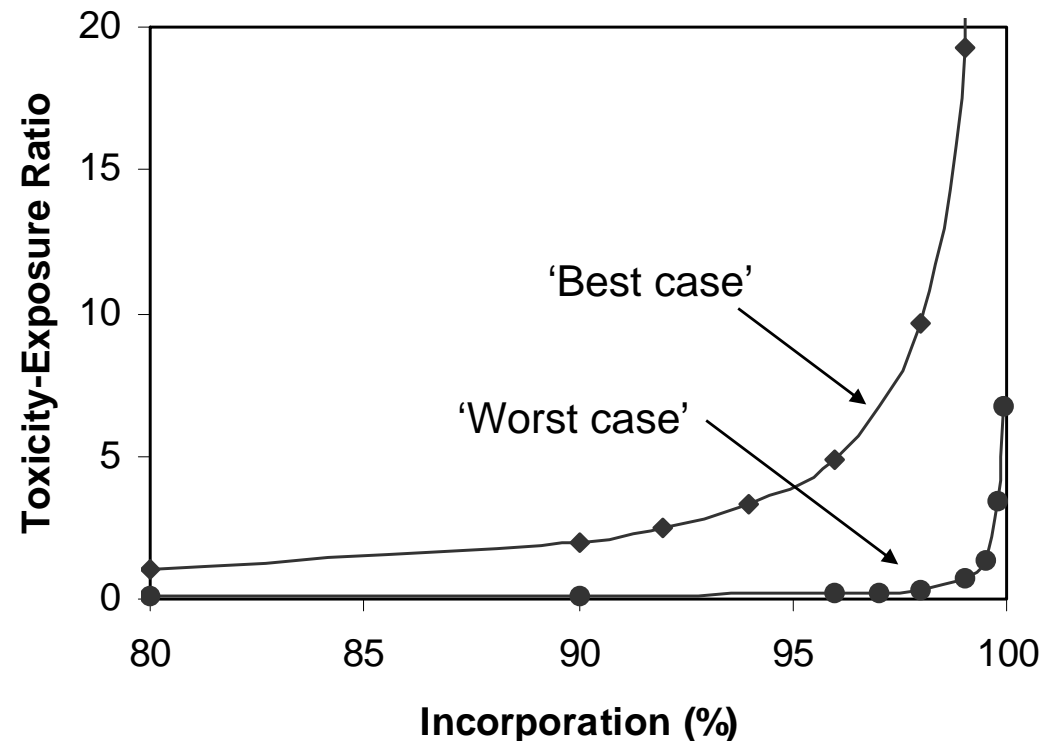
- ◆ Comprehensive
- ◆ Systematic
- ◆ Qualitative and/or quantitative
- ◆ Integrated
- ◆ Balanced
- ◆ Clearly communicated

Example 1: pesticide granules and birds

- ◆ Show how toxicity-exposure ratio depends on uncertain assumptions

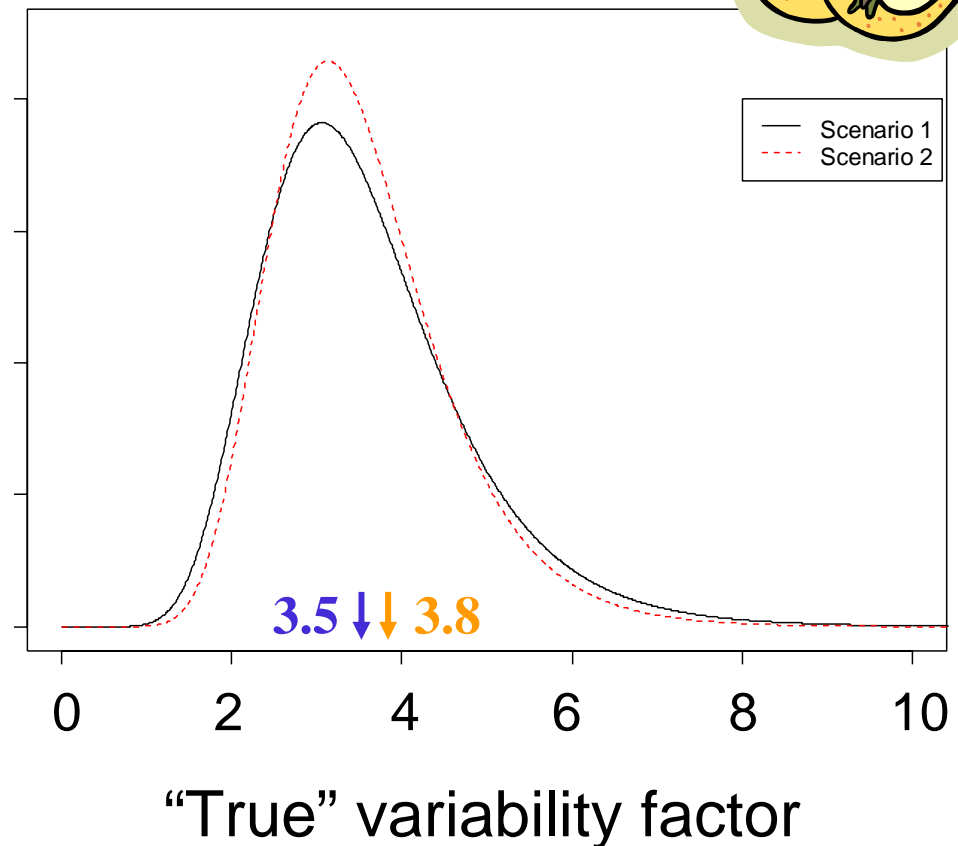
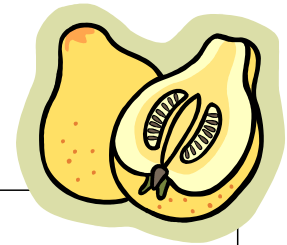
- *Degree of incorporation of granules in soil*
- *Best and worst case assumptions for other key parameters*

- ◆ Simple deterministic calculations



Example 2: variability factors for pesticide residues in food

- ◆ Average = 3.5
- ◆ Upper 95% CL for average = 3.8
 - CL expresses sampling uncertainty
- ◆ Probabilistic calculations
 - Repeated with alternative statistical scenarios (model uncertainty)
- ◆ Augmented by qualitative evaluation of other uncertainties



Example 3: insecticide and birds

- ◆ Deterministic calculations plus systematic qualitative evaluation of uncertainties

- ◆ *“substantial uncertainties, but overall the true risk is likely to be lower rather than higher”*

| Source of uncertainty | Direction & magnitude of effect on risk |
|------------------------------------|---|
| Toxicity variation between species | - - - / + |
| Residues on insects | - / + |
| Feeding rate assumed constant | - - - |
| Etc. ... | |
| Overall uncertainty | - - - / + |

EFSA SC WG Exposure Assessment

- ◆ Draft Working Document on uncertainties in exposure assessment
 - Why consider uncertainties
 - Types of uncertainties
 - Systematic identification of uncertainties
 - Key sources of uncertainty in exposure assessment
 - Tiered approaches to evaluating uncertainties
 - Communicating uncertainties
 - Implications for decision-making
 - Worked example?

- ◆ Draft to be circulated to SC & Panels shortly

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